Summary of EPA and Inter-industry Analytical Group Meeting
-- Draft, May 23, 1996 --

Overview

On April 26, 1996 representatives from EPA's Office of Science and Technology (OST) and Office of Wastewater Management (OWM) met with representatives from the Inter-industry Analytical Group (IIAG) to discuss detection and quantitation limits. IIAG is a consortium of trade associations and companies in the regulated community that focuses primarily on the impact of analytical chemistry issues on various EPA regulations. Other participants at the meeting included contractors, consultants, and other individuals invited to attend the meeting in order to provide additional perspectives. A complete list of meeting participants is provided as Attachment 1 to this summary.

The meeting was held to address IIAG's September 22, 1995 request for a meeting to further discuss their proposed alternate minimum level (AML). That request was submitted following an August 2-3, 1995 public meeting in McLean, Virginia on water quality-based effluent limits (WQBELs) set below the analytical detection limit.

A copy of the April 26th meeting agenda is provided as Attachment 2 to this summary. The meeting was focused on a discussion of 12 EPA concerns with the AML; these concerns (presented in Attachment 3) were forwarded to IIAG prior to the meeting in order to ensure that the meeting was as productive as possible. Following a discussion of these concerns, EPA presented preliminary results from a recent study of various detection and quantitation limits, including the AML, the minimum level (ML), and the method detection limit (MDL). The remainder of this report summarizes the discussions surrounding each of the 12 EPA concerns with the AML and the presentation of preliminary data from EPA's recent study. Copies of overheads presented by IIAG are provided in Attachment 4 to this summary; copies of overheads presented by EPA and its consultants are presented in Attachment 5.

EPA Opening Remarks and Meeting Objectives, *James Taft and William Telliard*

James D. Taft, Director of OWM's Water Quality and Industrial Permits Branch, and William A. Telliard, Director of OST's Analytical Methods Staff, opened the meeting by welcoming participants and summarizing meeting objectives. Mr. Telliard noted that the meeting served as a follow-up to the August 2-3, 1995 public meeting on WQBELs set below the detection limit. Mr. Telliard stated that, unlike the August meeting, in which EPA's role was to listen to ideas and comments presented by interested stakeholders, today's meeting was structured as a two-way dialogue in which EPA and IIAG could engage in an open discussion of concerns about the AML and ML, particularly within the context of regulating WQBELs that were below the limit of detection.

Mr. Taft added that, at the August 1995 WQBEL meeting, EPA stated its intent to issue revised guidance by late 1995 or early 1996.[1] Due to a variety of factors, including furloughs and other impacts of the

[1] Initial guidance was released in draft form on March 22, 1994. This guidance was entitled, *Draft National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limits Set Below Analytical Detection/Quantitation Levels*.

budget impasse, EPA was unable to meet its planned schedule. Mr. Taft noted that, as of the previous day (April 25, 1996), the Agency had received a final budget and is prepared to move forward with developing a final guidance document. Mr. Taft reminded meeting participants that the focus of the 1994 draft guidance was to address only those situations in which the method required for analysis of a regulated pollutant does not have a minimum level. Although the revised guidance will discuss ways in which a permitting authority should view values that are greater than the detection level but less than the quantitation level, Mr. Taft noted that this issue is principally a policy decision based on science and will not be discussed in the present meeting. Instead, Mr. Taft emphasized that the purpose of this meeting is to examine AML and other alternative approaches to those discussed in EPA's March 1994 draft WQBEL guidance.

Mr. Taft also stated that EPA is not contemplating the development of a rule or regulation explicitly intended to direct permitting authorities to adopt a specific position on the permitting component of the guidance. Instead, EPA intends to continue providing permitting authorities with some flexibility.

Although EPA was not prepared to provide a specific schedule for completion of a revised guidance document during the meeting, Mr. Taft indicated that he anticipates a 6 - 8 month time frame, which would include distribution of revised guidance, receipt of comments, and publication of a final guidance document and a response to comments document. Mr. Taft indicated that, in the near future, EPA would send meeting participants a letter outlining a tentative schedule for completion of this guidance.

Mr. Telliard concluded EPA's opening remarks by noting that in the last 1 - 2 years, EPA has received comments on the detection/quantitation issue as it relates to incorporation of methods into 40 *CFR* 136. Unlike the WQBEL guidance, this is a regulatory process in which EPA must respond to comments and is subject to litigation. EPA intends to respond to comments on this issue, as it relates to promulgation of the recently proposed wet chemistry and metals methods, as part of the regulatory process. *At this point Bill made a rather overt invitation to sue EPA (his words were along the lines of "we can all go visit the judge")... just for fun it might be interesting to see if we can come up with a way of keeping this challenge.*

IIAG Opening Remarks, *Babu Nott*

On behalf of IIAG, Babu Nott, a Senior Project Manager at the Electric Power Research Institute, thanked EPA for this opportunity to discuss the AML. Mr. Nott began by introducing and welcoming his counterparts from IIAG (identified in Attachment 1) and by summarizing IIAG's objectives for the meeting. Mr. Nott noted that IIAG's primary objective was to arrive at a scientifically sound definition or concept for a quantitation level that can be used for compliance monitoring purposes. Specific objectives include (1) responding to EPA's comments on the AML, (2) discussing the "data analysis" cited by EPA in its list of 12 concerns with the AML, and (3) determining "where we go from here".

Mr. Nott noted that EPRI has a long history of conducting research and development activities aimed at addressing the scientific uncertainties associated with methods for chemical analysis of pollutants, including uncertainties associated with analytical detection and quantitation limits. As a result of these activities, EPRI has developed a high quality database of interlaboratory data comprising analysis of 14 trace metals in 7 different matrices using a variety of analytical instrumentation, with a primary focus on atomic absorption methods. The body of work conducted by EPRI serves as a foundation for the AML concept developed by IIAG.

Mr. Nott then summarized activities that led to this meeting, noting they largely began in March 1994, when EPA released its draft WQBEL guidance. In that draft document, EPA introduced the concept of an interim ML that was equal to 3.18 times the MDL. Following release of the guidance, IIAG submitted comments to EPA on the ML in June 1994 and met with EPA to discuss its concerns about the ML in December 1994. At the public meeting in August 1995, IIAG offered its AML as a constructive alternative to the ML. Following review of requested information and documentation concerning the AML, EPA responded on April 16, 1996 with the concerns to be discussed today.

Mr. Nott closed his introductory remarks by suggesting that the group slightly modify the meeting agenda to present a summary of EPRI's position regarding the AML after the discussion of EPA's 12 concerns. All meeting participants agreed to this suggestion. Meeting participants also agreed to Mr. Nott's suggestion to discuss EPA's concerns in the order in which they appear in Attachment 3. Mr. Telliard added that the schedule allows for a 20 minute discussion of each concern, but some issues may require more or less time for discussion.

Discussion of First EPA Concern with AML, *Group*

EPA's first concern was that:

> There is no evidence to date that the AML provides a better estimate of the quantitation level than the ML. In fact, there may be some evidence that measurements at or near the detection/ quantitation limit provide the best estimate of these limits. Results to date indicate that data collected in the region of proportional error are not relevant to construction of detection and quantitation limits. Therefore, there is a heavy burden on proponents of concepts that use such data to demonstrate relevance, not through theoretical discussions, but with analytical chemical data.

Mr. Nott began this discussion by introducing Ray Maddelone of TRW; Mr. Nott further explained that Mr. Maddelone would lead IIAG's presentation of responses to EPA's concerns. Mr. Maddelone indicated that it would be useful for someone representing EPA's perspective to summarize the highlights and key points within each issue.

At Mr. Telliard's request, Dale Rushneck, of Interface and a consultant to EPA, and Dr. Henry Kahn, of EPA's Economic and Statistical Analysis Branch, jointly responded to this request. Mr. Rushneck began by explaining EPA's view that the current approach to quantitation limits is reasonable, and therefore, the burden of proof falls upon those who wish to challenge it. To date, that challenge has fallen short of a substantial demonstration that the AML offers any significant advantage over the ML. Mr. Rushneck acknowledged that there are some issues associated with the AML that could be debated, such as interlaboratory variability and tolerance levels, both of which would be discussed later in the meeting. Dr. Kahn added that the relevant region of interest is the region about the quantitation limit or the detection limit, depending on which limit is under discussion; therefore, the question of relevance goes directly to the relevance of data collected in a region that is far removed from that region, and hence, from the question at hand.

Mr. Maddelone replied that these statements were consistent with IIAG's interpretation of EPA's first concern, but cautioned that IIAG was at some disadvantage in responding because it does not have a fundamental understanding of the data set on which EPA based some of its statements. Mr. Maddelone also questioned the criteria that were used to make the assertion of a "best estimate", noting that at the

August 1995 meeting, IIAG presented the properties that it believes are most appropriate for a quantitation level concept. He further stated that when IIAG has assessed the AML and more rigorous statistical approaches such as the Hubaux vos model and the model on which Robert Gibbons and David Coleman are working, they have found all of these to better match those properties than does the ML. Mr. Maddelone also noted that IIAG strongly believes that, from a chemists standpoint, it is important to predict the quantitation level that will fall into the constant region of the standard deviation vs. true concentration curve, and that in evaluating this region, the curvilinear model, which has a portion that is relatively constant in the standard deviation of concentration, a transition zone, and a portion that is relatively linear in standard deviation vs. concentration, is most appropriate. Therefore, without data points in the constant region and the proportional region to develop this model, it is impossible to predict a quantitation level that meets the basic criteria established by ACS, Currie, and many others. Namely, it is important to that a quantitation level be related to a known or specific relative standard deviation (RSD).

Mr. Rushneck disagreed with this assertion, noting that the context of this meeting is to establish a compliance evaluation threshold (CET) when the WQBEL is below the detection or quantitation level, and in that context, the quantitation limit is not an appropriate number. Mr. Rushneck suggested that in effect, EPA has made a policy decision to move to the quantitation level and provide greater tolerance to permittees. Mr. Rushneck added that the concept of a quantitation limit being defined on the basis of 10% RSD is somewhat of an arbitrary choice because, as all analytical chemists know, there are many measurements that will not produce RSDs of 10%. Given this fact, requiring 10% RSD is an untenable position. In summary, Mr. Rushneck concluded that a one-sided distribution appears to be most appropriate for a CET, and EPA has essentially granted an additional factor by allowing for compliance evaluation at the quantitation level.

Mr. Maddelone responded that the supposition about not using the quantitation limit as a CET is not something IIAG would follow and is different than what was previously stated by EPA.

Chuck White, of EPA's Economic and Statistical Analysis Branch within OST, responded by stating his perspective that the quantitation limit is not an appropriate concept for a fixed point measurement. Mr. White elaborated by noting that there is a relative standard deviation that is relative to the true concentration that is measured and a permit limitation that is fixed. He argued that what IIAG saying with its criteria is that a measurement above a certain permit level will have a certain true concentration variation associated with it, and a measurement below that permit limit will have a smaller true variability associated with it. This implies that the lower concentration is a worse measurement because of its RSD, but one to go back to absolute measurements, it is a better measurement. Chuck stated that EPA simply doesn't agree that RSD is an appropriate measure of variability when addressing ??*I missed what he said here!*.

Mr. Maddelone indicated that he was somewhat confused because this argument does not follow Dr. Lloyd Currie's concept, which was adopted by the American Chemical Society (ACS). He also added that in these discussions, it is important not to focus on a specific number (e.g. 10%), but rather on a concept, and that the concept in this context is the RSD. Dr. Kahn responded that we need to be very clear about the concepts, because ACS' concept is based the variability associated with a zero measurement. EPA does not necessarily state that the MDL is compliant with the ACS concept, but rather, that it is an approximation based on the ACS concept. In fact, the variability provided in EPA's procedures appears to be substantially greater than that advocated by ACS. At this point, Mr. Nott interjected and suggested that the group not get sidetracked into a discussion of ACS perspectives and

focus, instead, on the concerns cited by EPA.

At this point, Mr. Rushneck and Mr. Maddelone engaged in a discussion of the curve that is most appropriate for use in modeling detection and quantitation limits. On this issue, it was agreed that the primary area of dispute is in the area of variability; there was general agreement on the shape of the curve and the need to study concentrations in the area of interest.

Mr. Rushneck noted that, with its MDL procedure, EPA accomplishes this through an iterative process in which the calculated MDL must be within a factor of five of the level spiked. This is because, as Professor Gibbons has noted, if the MDL procedure is conducted using concentrations that are well above the transition region of the curve, the calculated values largely over estimate the true detection limit. EPA's studies have shown that this "flaw" in the MDL procedure is equally applicable to the AML procedure. Mr. Maddelone responded that the AML procedure requires the use of concentrations that are in the more appropriate region of interest. Again, Mr. Rushneck reiterated that the MDL contains the same requirement that measurements be made in the region of interest.

Following this discussion of appropriate spiking concentrations, Mr. Maddelone observed that the iterative MDL procedure is essentially regression study, and questioned why EPA would not want to use the statistical power offered by a formal regression analysis. Mr. Rushneck responded that, as a practical matter, laboratories are normally able to achieve the proper spiking level on the first or second attempt, and therefore, a formal regression analysis, as dictated by the AML, is unnecessarily costly. Mr. White added that as a practical measure, one has to assume some model of the relationship between concentration and variability and to assume it for all pollutants and all situations. In reality, this model may not always be the same, but this would require an inordinately impractical amount of judgement decisions that are unneeded because of the relatively minor differences that such specifically tailored models would have on the final outcome. In reality, the general knowledge that variability increases as concentration increases is what is important. In some cases one can measure the true concentration, find variability about zero and indeed show that we are not prosecuting people for false positives. *this needs some editing!*

David Coleman responded that this argument seems fine for the MDL, but the ML, which is equal to the MDL x 3.18, moves into a higher region of the curve for which there is no model. Right now EPA is assuming a model based on constant standard deviation, but a few minutes ago we agreed that this does not hold over a broad range of concentrations. If we don't know where the transition range is, then how do we know how well that 3.18 factor holds?

Mr. White stated that he personally would do away with the 3.18 value and just worry about the calibration and identification of pollutants for a quantitation level. People generally use the term quantitation to refer to RSD. as far as Chuck's concerned, if you've got variability within the bounds that people generally consider acceptable, then you've got enough.. **obviously need to come back and deal with this!!!** Chuck then tried to disclaim his position as Chuck, not EPA, but Pat Nixon stated that as far as he's concerned, Chuck is EPA!

Mr. Nixon asked to clarify a question, noting that he thinks what he is hearing from EPA's statements thus far it that, when discussing these issues in the enforcement and compliance context, the important question is not whether a pollutant can be measured, but rather, whether it can be detected. Mr. Nixon asked if he was hearing these statements as a firm matter of policy, and if so, cautioned that these perspectives differ strongly from those previously stated by the EPA Office of General Council (OGC).

Mr. Taft responded that these statements are not being made as a matter of final policy; rather, they are being discussed in the context of policy decisions that may be made appropriately on the basis of sound science. Mr. Taft reminded the group of his opening statements in which he noted that the way in which these issues will be regarded in an enforcement and compliance context are not the primary focus of discussion for today. The primary focus is, instead, on the scientific principles underlying the MDL, ML, and AML. As Mr. White stated, the opinions he voiced were his own and not that of the Agency.

At this point, Dr. Robert Gibbons, a consultant to IIAG, attempted explain what he perceived as fundamental problems with the ML, by explaining some of the differences between the ML and the AML concepts. Using the white board to illustrate his point, Dr. Gibbons noted that the:

$ML = 10\ \sigma_0$	(or 10x the standard deviation of blank measurements, using a proxy of measurements at a low concentration),
$AML = 10\ \sigma_{CL}$	(or 10x the standard deviation at Currie's critical level, a level similar to the MDL), and the
$L_Q = 10\ \sigma_{LQ}$	(or 10 x the standard deviation at LQ).

and that LQ is the "real thing"; it is the level that is the RSD at 10% or whatever other numerical value is of interest.

At this point, the tape ran out for awhile, and unfortunately, my notes are littered with holes where I couldn't keep up with the discussions and with the material being written on the board... Barry or someone else will need to fill in my gaps!!! Rather than expend too much energy, I've pretty much left my notes unedited in the hopes that Barry can fill them in more efficiently than I can.

the null hypothesis, Ho, is that if the true value is equal to 0, then we can use the MDL equal to 3.18 σ_0.

$MDL = 3.18\ \sigma_0 \times (1 + 1/n)^{1/2}$

Dr. Gibbons then noted that the problem with the ML is that it depends upon where one does the study because if you get into the area of proportional variance it can give you a bad quantitation limit. The AML, however, resolves this problem by starting with/estimating Currie's critical level to find the point at which RSD = x%. The danger is that from one lab and one instrument, the estimate of σ_0 can vary. The ML is a 'crummy' quantitation limit; it was intended to be like Currie's detection limit.

The AML anchors the estimate of σ at ???. It is an intermediary between ??? and L_Q.

Joe Slayton, of the Central Regional Laboratory in EPA Region III, questioned Dr. Gibbon's statement that the ML is a "crummy" quantitation limit, specifically asking if Dr. Gibbons had considered the fact the ML concept includes the ML value in the calibration curve. As Dr. Gibbons started to respond that all of these other methods really do need a full calibration curve, Harry McCarty of SAIC and a consultant to EPA, clarified for Dr. Gibbons that the term "calibration curve" as used by analytical chemists differs from the term as used by statisticians such as Dr. Gibbons. Dr. McCarty explained that when chemists run the method, they do not calculate an MDL, an ML or an AML. Rather, they simply perform the method and send the results in to their clients or permitting authority. The calibration curve to which Mr. Slayton and other chemists in this meeting are referring is the curve that is run each time the analysts performs the method. The current practice is for the analyst to calibrate the instrument with

each sample batch, and to include the ML at the lower end of that calibration curve. This practice ensures that, at a minimum, there is a batch-specific indication of the reliability of measurements at the quantitation level; either the laboratory is capable of meeting the required ML or it is not.

Mr. Maddelone responded that this statement is not necessarily true because the calibration curve is not run in a specific matrix; it is performed in reagent water. Dr. McCarty responded that the AML is not really matrix-specific either because it is not determined for each batch for each matrix, nor is it determined when the laboratory performs routine instrument maintenance. Dr. McCarty noted that laboratories using a method on a particular effluent sample are going to report an AML that resulted from a study six months, one year, or many years earlier and, in all likelihood, this study will not have been performed in the same matrix as that currently being analyzed and reported or under analytical conditions that are identical to those currently used by the laboratory.

Mr. Maddelone responded that this is analogous to IIAG's argument about the single laboratory MDL procedure, where the concern is that if a laboratory fully optimizes the instrument and analytical conditions, and runs the MDL in order to achieve a specific measurement criterion, the procedure provides no indication about how well that laboratory can perform under routine situations. This concern is an inherent concept of the AML in that the samples should be provided to the laboratories in blind fashion in order to measure typical performances.

Dr. McCarty responded that he was not referring to special measures to optimize performance for a specific QC audit. Instead, he was referring to routine instrument maintenance such as changing a column, cleaning the source on a mass spectrometer, etc. The advantage of the ML concept is that when a laboratory performs these routine maintenance functions, they are required to perform a new instrument calibration and demonstrate their ability to measure the ML. Presumably laboratories would not be required to run a new AML determination in these circumstances because it would be excessively burdensome; the ML concept, however, addresses this ongoing source of variability.

Mr. Coleman then responded that this is one of the reasons for using interlaboratory data; different instruments and different laboratory staff contribute to different sources of variability. Mr. Rushneck commented that use of an interlaboratory factor also is possible with the ML.

A brief discussion ensued about the lack of RSD calculations associated with the ML. Mr. Maddelone questioned how the RSD is calculated at the ML. Mr. Rushneck responded that it is not calculated because it is not needed. EPA requires calibration as a minimum; if people want to measure RSD at the ML it can be done, but it is not required.

Larry LaFleur, of the National Council of the Paper Industry for Air and Stream Improvement, Inc (NCASI) observed that the discussion at this point is really about a quality control issue that easily can be dealt with in the laboratory. For example, depending on your data quality objectives, you could set the lower calibration point at either the ML or the AML.

At this point, Mr. Telliard noted that the discussion had begun to move well beyond the originally planned 20 minute schedule for each of EPA's 12 concerns. He added that the discussion thus far had been highly productive, but in the interest of ensuring that all points could be covered during today's meeting, he would like a consensus decision as to whether this issue should be further discussed or whether it was time to move on to the next item on the list. The group agreed to allow one more point to be made about this issue before moving onto issue number 2. Specifically, Mr. Coleman indicated

that he wanted to return to the question about EPA's meaning with the phrase "best estimate". In particular, Mr. Coleman was interested in hearing the criteria with which EPA judged the AML, reminding the group that IIAG had presented their criteria for such an assessment at the August 1995 public meeting. Does EPA have a similar table?

Dr. Kahn responded that a statistical "best estimate" approach was not in mind when this was written; instead, this is really more of a general analytical chemistry perspective that measurements at or near the detection or quantitation limits are really the best estimate of the these limits.

Discussion of Second EPA Concern with AML, *Group*

EPA's second concern was that:

> The AML is too complex. The required statistical sophistication will reduce the utility of the AML because the AML will not be understood by the bench chemist. Use of the AML by unsophisticated users will result in unpredictable results.

Mr. Nott began this discussion by requesting that EPA once again highlight the key concepts of its purpose. Mr. Rushneck began this discussion by noting that he has worked with 4-5 laboratories and consulted for more than 18, and he has a good feel for what goes on in the laboratories. Mr. Rushneck stated his opinion that a typical bench chemist will have no idea how to handle the AML. Mr. Rushneck conceded that a chemist with Mr. Maddelone's experience could handle the AML, but typical bench chemists could not. Mr. Slayton added that, in his experience, based on performing inspections of many facilities, it is critical to keep the procedure simple and focus on the major sources of error not the minor sources. Specifically, Mr. Slayton suggested that the amount of error that is being addressed by the difference between the AML and the ML is trivial when compared to the errors that can be made by sampling and laboratory staff. Mr. White added that, as indicated earlier by Mr. Taft, the purpose of this discussion is to address unpromulgated quantitation levels in relationship to WQBELs.

Mr. Maddelone responded that IIAG was proposing a two-application type of approach, in which

- EPA would use the AML to determine the appropriate quantitation level when developing and promulgating methods, and

- Permittees who need to conduct a site-specific study could also perform an AML study, in much the same way that EPA has currently allowed determination of a site-specific MDL/ML study.

Mr. Maddelone also added that IIAG believes the calculations involved in performing the AML are far less complicated that other calculations required by EPA in analytical measurements, such as those used for isotope dilution GC/MS analyses. Modern ICP/MS and GC/MS instruments are serious "black boxes". Mr. Maddelone further noted that IIAG believes that overall accuracy and reliability are more important than administrative convenience, and suggested that measures could be taken to facilitate proper use of the AML. For example, he noted that the primary user of the AML would be EPA, much as it is the primary user of the ML. A special protocol could be developed, however, for use by permittees that need to compute site-specific AMLs, and that technical support could be provided to these permittees in much the same manner that is currently being provided.

Dr. McCarty noted that one advantage of the MDL/ML concept over the AML concept is that the MDL can serve as a basic tool verify that laboratories are capable of adequately performing the method; in other words, the MDL can serve as a minimum performance requirement. Mr. Maddelone responded that, if the laboratory is conducting self-monitoring analyses, it is by definition a laboratory that is qualified to perform the method. IIAG is not asking the laboratory to do anything more than any good analytical chemist can handle; the AML is simply a method of standard additions calibration curve, and the tools for evaluating this curve are not terribly difficult to use. The AML is not intended to be a tool for qualifying minimum laboratory performance.

Mr. LaFleur noted that, once again, the discussion had moved off track to an issue that is easily resolved by laboratory quality control requirements; the AML was never envisioned as a minimum QC requirement. Mr. LaFleur further clarified that if a permittee felt that they could not achieve the ideal detection limit or the detection limit derived by EPA based on its own studies, due to matrix effects or other reasons, the permittee would conduct a site-specific AML study as a basis for requesting a site-specific limit.

Mr. Slayton reiterated his desire to keep the process simple enough that permittees would not be required to rely on a commercial laboratory. Mr. Nott concurred with this desire, but added that it cannot be the overriding objective. Mr. Slayton and Mr. Rushneck both responded that they do not wish to leave the impression that accuracy and reliability are less important than administrative convenience, and they expressed their belief that a quantitation limit based on the MDL provides accuracy, reliability, and convenience. In response to a specific question by Mr. Nixon to clarify the meaning of "accuracy", Mr. Rushneck replied that he believes it is a fair representation of quantitative accuracy.

Mr. Rushneck requested clarification from Mr. Maddelone about an earlier statement regarding IIAG's interlaboratory studies. Specifically, Mr. Rushneck asked if he was correct in understanding that laboratories would be sent blind samples and would provide calibration data. Mr. Maddelone responded that no, laboratories would be sent blind samples for analysis within the normal operating conditions of the laboratory, the data would be sent back to the person running the study, in just the way that the EPRI studies were run. Mr. Rushneck requested further clarification about the purpose of these studies; were they conducted to develop QC requirements or to calculate detection and quantitation limits? Mr. Maddelone responded that these studies, which were conducted over the last six years or more, were conducted to calculate detection and quantitation limits. Mr. Maddelone added that he has all data from these studies in a spreadsheet.

Discussion of Third EPA Concern with AML, *Group*

EPA's third concern was that:

> Software for establishing the AML is "black box," resulting in largely uncontrolled results except in the hands of a skilled user.

Mr. Rushneck began this session by noting that the "black box" issue had already been touched upon in an earlier discussion; he also recognized that the software does not necessarily have to be a black box and acknowledged the relevance of Mr. Maddelone's comment about the black box nature of modern analytical instrumentation. The point that was being made with this comment is that the AML is so much more complex than the MDL, and the way the AML would be utilized is to plug numbers in and push

a button, whereas it is possible to get on the phone with laboratories discuss their MDL procedure to determine what went wrong. The black box nature of the AML process would preclude such technical support. Instead, it would require a thorough examination of the process and the data to determine what the laboratory did incorrectly.

Mr. Maddelone responded that all equations used to determine the AML have been published, so it is not entirely clear to IIAG why this is a "black box". Also, Mr. Maddelone reminded EPA that the AML approach was based on the fact that EPA would be the primary user of the AML concept, so the need for technical support should be minimal. Finally, Mr. Maddelone indicated that it is not clear how a laboratory would get uncontrolled results if, in fact, the AML is a black box, because the results would be generated automatically by following the procedures necessary to collect the data that feed into the calculation. Mr. Maddelone then presented a spreadsheet that showed each calculation used to derive the AML.

Barry Eynon, a consultant to EPA, responded that the spreadsheet is not the difficult part of the AML calculation. The difficult part is the procedure for estimating the variance of the calibration curve. Mr. Eynon noted that the AML procedure uses STATCALC which truly is a black box at this point. For example, he noted that it is not clear if a weighted regression is being used, and if so, what weights are being used in that regression. Mr. Maddelone and Mr. Coleman responded that the standard approach is being used. They further explained that STATCALC is an EPRI-developed program that implements ASTM D-*277??- can someone get correct reference here*, the outlier testing protocol; it is equivalent to the *IMVS??* program. Mr. Eynon responded that the spreadsheet assumes that the user already has the parameter estimates and the form of the curve of variance vs. concentration and that the user just plugs in and solves for the AML. Mr. Eynon indicated that although he has no problem with the Excel spreadsheet, he feels that additional information is needed about the STATCALC program because it is part of a two step process for determining the AML. Mr. Maddelone stated that Dr. Gibbons is in the process of beta testing a completely stand-alone program for calculating the AML and that this program includes options for selecting the most appropriate curve, including an automated best fit selection. It was agreed that further clarification of these statistical areas and procedures would address many of EPA's concerns in this area.

Discussion of Fourth EPA Concern with AML, *Group*

EPA's fourth concern was that:

> Calculation of the AML involves fitting the curve of precision *vs* spike concentration, including both the selection of the form of the curve and fitting the curve to the data. To minimize costs, and in the absence of interlaboratory data, the AML proponents suggest using single-laboratory data with an interlaboratory multiplier. In this construction, the amount of data proposed (triplicate determinations at four levels) is marginal at best for distinguishing between competing mathematical curve forms, yet the choice of curve form can have a significant effect on the resultant AML. There is not enough data to show whether one curve form can be selected as being both robust and flexible enough to be adopted as the standard form, yet the proponents of the AML leave selection of the curve form at the discretion of the user, a highly undesirable situation.

Mr. Eynon initiated this discussion by highlighting EPA's key points in this statement. In particular, Mr.

Eynon functional form of the variance curve intrinsically will affect the definition of what is calculated as the AML, and if that curve selection process in wrong, the AML will be more likely to provide the 10% RSD criterion than will the ML. In response to a question from Mr. Coleman, Mr. Eynon noted that different data sets will lead to different magnitudes of this problem, and the magnitude of the problem is largely dependent upon the amount of data that one is willing to gather to properly estimate the curve. There is a distinct trade-off between the amount of data that one is willing and financially able to collect and the ability to discern the correct functional form of the curve.

On behalf of IIAG, Mr. Coleman responded that the industry group had discussed this issue and agrees that, to some degree, it is a legitimate concern. Stating that he himself has wondered about this issue, Mr. Coleman indicated that he has conducted a full simulation. He also pointed that we already have a model that we're dealing with when we're addressing the ML, and that is the constant standard deviation, so the issue of mis-specification of the correct curve is already an issue with the ML and we've already agreed that we have a hockey stick; the question is where you are hockey stick. The exponential has more flexibility; it doesn't force it to go up within the region of interest. In fact, the standard deviation data are fairly stable, and that will be reflected in the data that are derived. Mr. Eynon responded that the exponential is that eventually it will be fitted to relative standard deviation that eventually goes up and that he doesn't believe this is a valid model. It may not practically make any difference because it may go up in an area that is beyond the area of interest in the curve, but suggested that use of a good curve such as the quadratic curve described by *Rocky and Monzano??*, which can be thought of the constant variance due to the blank plus the proportional variance due to the analysis of the sample. Mr. Coleman, Mr. Maddelone, and several others from IIAG expressed their agreement with Mr. Eynon on this point. Mr. Eynon added that IIAG's original expert paper provided little guidance on how these forms were to be selected. To some extent, the information provided to EPA today has contributed to a better understanding of various aspects of the AML, but the appropriate selection of a curve is still an important issue that needs to be properly addressed.

Mr. Coleman then presented a summary of his findings based on a simulation of 24 different curve fits with 5 replicates at each of five concentrations. The data were presented as standard deviations versus true concentrations. His results showed virtually no difference between the exponential and straight line fits for nearly all data points, suggesting that the magnitude of error that may result from selection of the incorrect curve could be inconsequential. Dr. Gibbons noted that the situation in which the model specifications most likely to have a noticeable impact is in the linear equation containing a negative intercept. Mr. Eynon agreed, noting that this is one of the points EPA had made in its list of 12 concerns with the AML. Dr. Gibbons suggested that the linear model is probably an inappropriate model, and would not be allowed in the AML program. All parties agreed that the Rocky and Marzano model intuitively seems as good as any, but additional testing would be necessary to confirm this.

Kathleen Stralka, of SAIC and a consultant to EPA, requested clarification about the software used to select an appropriate model. Dr. Gibbons responded that the software is now in the prototype stage, and at this point contains several curves. Additional curves can be added. Dr. Gibbons envisions that there will be two versions of the AML software. One version will use a single curve or automatically select a best fit curve; the other version would allow the user to evaluate a variety of curves.

At this point the group agreed to conclude the discussion about EPA's fourth set of concerns with the AML. In this closing discussion, Mr. Maddelone expressed disagreement with EPA's assertion that the interlaboratory multiplier is a cost-saving device, clarifying that instead, the interlaboratory multiplier was designed to provide flexibility to permittees needed to conduct site-specific detection limit studies. IIAG's

intent is that EPA conduct full interlaboratory studies when establishing AMLs for promulgated methods.

Discussion of Fifth EPA Concern with AML, *Group*

EPA's fifth concern was that:

> It is unclear whether the statistical fitting process for the precision curve has been addressed sufficiently. Issues of what weights are appropriate and the non-normality of standard deviation/variance data, even when the concentration data are normally distributed, are not addressed in any of the discussions provided by the proponents.

In general, there was unanimous consensus that enough had already been said regarding this concern. Mr. Eynon, however, did note that if the original data are normally distributed, then the standard deviation will be non-normal. This could require some custom-fitting, which is largely impractical. The weighting issues and the distributional issues must be addressed as part of the AML procedure. Mr. Coleman responded that IIAG has given some thought to this concern but feels that the practical consequences of the problem are inconsequential.

Discussion of Sixth EPA Concern with AML, *Group*

EPA's sixth concern was that:

> One criticism of the MDL has been that it is sensitive to the spiking level. However, preliminary results from bootstrap simulations using metals data show the AML to have at least as much variability as the ML, particularly when using the design with three measurements at each of four concentrations. The selection of the four levels also introduces variability. If these levels are chosen inappropriately, not only can high AMLs, low AMLs, and AMLs equal to zero be produced, but negative AMLs also can be produced.

At the outset of this discussion, it was generally acknowledged that the key points of this issue had been touched upon already during previous discussions in that if you conduct either the MDL study or the AML study incorrectly, you can get inappropriate MDL or AML values. Therefore, Mr. Maddelone led off the discussion by presenting IIAG's rebuttal to EPA's concern. Specifically, Mr. Maddelone noted that the key point IIAG would like to make is that the AML does anchor L_c, the starting point for the AML, when a regression model is used, whereas the MDL is a "variable beast" in that the result obtained depends upon the spike level used. For any set of data, the points over a range in a calculation will result in only one AML, but the same set of data, it is possible to obtain multiple MDLs depending on the values chosen. Mr. Maddelone acknowledged EPA's concern that improper spike levels can produce an inappropriate AML, but again reiterated that if a proper series of spike concentrations is used, only one AML can be produced, whereas any data set consisting of more than one point will produce multiple MDLs. Mr. Eynon disputed this assertion, suggesting instead, that the if the MDL procedure is properly followed by working down the curve to the lowest value that meets the criterion, then only one value can be obtained. Dr. Gibbons responded that the MDL specification for a factor of five may be too large, and in practice people spike 70 compounds at a single level and never perform the iterative procedure.

Dr. Gibbons further stated that IIAG is not suggesting that chemists should use concentrations that are 10 times greater than the typical quantitation limit, Many times he has used such examples in his papers because those are the standard calibration data that are available and they are free. Why go out and perform a $100,000 study. Mr. Rushneck responded that EPA could do the same thing with the AML that Dr. Gibbons has done with the MDL, namely choose calibration data that are well above the range of interest and publish a paper on that. Dr. Gibbons responded that there was no guidance on that, and Mr. Rushneck countered that the MDL procedure explicitly limits the range of concentrations that can be used. Dr. Gibbons added that the AML procedure ensures that, as long as the analyst chooses values in the appropriate range, which could even include zero, only one AML value can result, whereas, if you choose a value that produces no instrument response when using the MDL procedure, you will get a value of zero. Mr. Eynon responded that wouldn't try to calculate sigma at that point. Dr. Gibbons argued that people have been known to misapply the MDL procedure, and cited a recent conference in Wisconsin in which someone stated that they find lower MDLs for Lake Michigan waters than they do for their instrument detection limit. When he asked how that could be, they said it was because they get six zeros and computed a zero number; this model would not allow such an error to occur, and in fact a zero-zero point is an acceptable value in an AML calculation.

Following a brief discussion about the details of this calculation procedure, Mr. Nixon noted that IIAG is concerned about protecting itself from abuse by the unreasonable person, such as that described by Dr. Gibbons. Mr. Eynon commented that, perhaps, the simplest solution would be to improve the quality of the MDL by issuing guidance with clearer statements to the effect that "thou shalt not do...". Mr. Coleman responded that the AML computation explicitly provides the needed level of protection. Mr. Eynon also noted that, given that variance will increase as you increase concentration, the AML will simply result in a slightly conservative upward allowance in the ML.

Dr. Gibbons responded that this is true for the MDL, but multiplying that blank standard deviation by 10 to get at a quantitation limit has little to due with quantification, which is about signal to noise ratio. What is the signal to noise ratio when the only noise you've got is the blank (or zero) and you are now at an active concentration climbing the hockey stick. Mr. White countered that the English definition of quantitation is that it has to do with a number that is considered to be reliable. There has been a lot of literature stating that quantitation has to do with RSD as far as s/n, but that is not necessarily the only definition of quantitation limit. Mr. White once again suggested that an alternate definition of quantitation might be that you can determine that the result is different that zero, that you have a reliable calibration curve, and that you can identify the pollutant. Dr. Gibbons asserted that this definition was flawed because the null hypothesis that the true concentration being greater than zero has little to do with a quantitation level. This hypothesis might be relevant to a test of the critical level or a perhaps even to a detection level. Mr. Eynon suggested that Dr. Gibbons turn the question around and ask what a quantitation level has to do with a test that a pollutant is above a WQBEL. Dr. Gibbons responded that this is the policy implication of the question, and agreed that could be an appropriate hypothesis to test the question of whether a water quality standard at concentration X is exceeded in the sample. As phrased by EPA, however, the ML is a quantitation level.

Mr. Telliard and Mr. Rushneck noted that the purpose of the guidance is to determine the appropriate level for deciding that a WQBEL has been violated. In that context, something like a detection level or a critical level is the level at which that test should be performed, and EPA has moved to the quantitation level as a matter of policy. In other words, by going to the ML, EPA has already guarded against the irrational individual hiding in the bushes with his 17 zeros. Mr. Telliard also noted that there are a multitude of states that all do it differently, and they may choose to look at the MDL as the trigger for

their activities. At the WQBEL level, the MDL itself would have been an adequate violation.

Mr. Taft clarified that the WQBEL limit that is calculated goes into an NPDES permit, and there is no willingness to revisit that concept. The March 1993 guidance addressed the question of how to determine if that limit had been exceeded. He reminded the group that EPA has withdrawn that guidance and is now revisiting that concept and would like to articulate a detection level concept and a quantitation level concept. How those are regarded in an enforcement and compliance manner is not an appropriate subject for discussion by the group assembled today. Comments from individuals regarding appropriate compliance monitoring questions are individual opinions only; EPA has not yet arrived at any decision from a national standpoint.

Mr. Nott suggested that since EPA's point number eight largely deals with these policy issues, we should skip that point.

Discussion of Seventh EPA Concern with AML, *Group*

EPA's seventh concern was that:

> Other than the study of trace metals by ICP/MS conducted by EPA's Engineering and Analysis Division (EAD), the Office of Water is unaware of any study that provides a database that allows a direct, fair comparison of the ML, AML, LOQ, and other quantitation limit concepts. In the absence of fair comparative data that demonstrate a clear and recognizable advantage to the AML or any other concept, EPA cannot justify changing to an alternate concept.

By way of clarifying this issue, Mr. Rushneck noted that the point was directed at the lack of any existing database that contains seven replicates across a wide range so that you could calculate MDLs in the CFR procedure and could construct AMLs with the same data in order to allow a 1:1 comparison. Mr. Maddelone agreed that IIAG had nothing like that, but that the EPRI data does allow calculation of pooled single-operator MDLs. Mr. Maddelone then presented IIAG's perspective on EPA's concern.

First, Mr. Maddelone noted that IIAG could not verify the veracity of the comment because they do not know what criteria EPA is using to evaluate the ML, AML, and other concepts. For any *set* of data, a set defined as a set defined as multiple replicates at those concentrations, it is possible to calculate multiple MDLs but only one AML, and for that matter, only one L_c, and one L_D. In addition, he made the point that when addressing quantitation levels, its necessary to compute the RSD at that level, but that the ML does not provide such information. Mr. Maddelone noted that for EPRI data sets suggest that the RSDs for river water averaged 13% and 10.6% for ash pond overflow. Mr. Eynon observed that this is an interesting question; he will go back to his data and try to estimate the RSD at the ML. Mr. Maddelone expressed his interest in receiving this data and offered to provide EPA and Mr. Eynon with the EPRI data sets.

In response to a concern raised by Mr. Coleman, Mr. Eynon and Mr. Kahn pointed out that the ML was not intended to guarantee 10% RSD. Rather, it is 10 σ at zero, but if one assumes that standard deviation is constant (as does ACS) then it theoretically translates to 10% RSD.

Dr. McCarty noted that in the context of the WQBEL guidance, if the answer is 10% RSD at X ppb, one can construct a series of confidence windows about which the value would still exceed the WQBEL. This

is where the policy question arises.

Mr. Maddelone commented that IIAG is not interested in what the number is; they could care less about the number; IIAG is instead interested in ensuring that the number is based on good science and is defensible. He added that if the numbers turn out that everyone has to buy an ICP-MS because that is what the AML is, we'll take that hit. But we want to know that when we calculate that number, we want to know it is based on some science and is defensible as chemists and statisticians.

Mr. White disputed the use of RSD to evaluate the quality of quantitation limits associated with fixed compliance numbers. Mr. White stated that the IIAG argument suggests that a high measured result with a low RSD but a high true SD is a better number than a low measured result with a lower true SD but a higher RSD. In terms of compliance with a fixed limit, this is not an appropriate measure.

Mr. Maddelone and Dr. Gibbons countered that if the RSD of the AML is +/- 50%, then this would suggest the method is not applicable to this matrix. It is not an acceptable quantitation limit and that it would be inappropriate for EPA or state permitting authorities to enforce compliance standards at this level.

Discussion of Eighth EPA Concern with AML, *Group*

EPA's eighth concern was that:

> The AML has been advanced as the compliance evaluation threshold (CET) to be used when the water quality-based effluent level (WQBEL) is below the analytical limit of detection. The AML concept allows for false negatives and sets the CET at 10 sigma. EPA has received persuasive arguments that allowance for false negatives and a 10 sigma multiplier are unnecessary for setting the CET. If EPA accepts these arguments, the need for the AML (and the ML) are eliminated in favor of a detection or critical level as the CET.

Discussion of this issue was limited because it had been previously addressed and largely agreed that this was a policy issue that was beyond the scope of this meeting. Mr. Coleman requested that IIAG be provided with copies of the "persuasive arguments" cited by EPA; he also asked who was making these arguments. EPA responded that they had received these comments from a variety of sources, including a well-articulated document from Joel Karnofsky, a consultant to EPA and a variety of other public and private Agencies and organizations. A copy of Mr. Karnofsky's document was provided to interested participants at the meeting. *(Actually, I'm not positive if we did that or if we chose to sit on it... Dale, do you know?*

Mr. Telliard noted that a number of states have expressed different perspectives on this issue, and that many states are perfectly satisfied with the "systems" that they are now using and see no reason to change. Mr. Nixon responded that although Bill has a good point about state personnel who say that states are perfectly happy with the system, EPA needs to move towards a far more discriminating inquiry. The issue should not be a popularity contest, and EPA should not accept a system that is comfortable but may not be appropriate.

Joe Slayton added that the reality is that states cannot wait until EPA makes a national decision regarding the enforcement and compliance issues associated with regulating WQBELs below the detection or

quantitation level. Mr. Taft observed that this is a good point, and that, whatever EPA finally advocates in the final guidance, it may be appropriate to discuss the pros and cons of some of the other approaches that have been proposed in the response to comments.

Following a suggestion by Mr. Telliard that the group take a 15 minute break before a working lunch, Mr. Rushneck requested the opportunity to close with one final point. Specifically, Mr. Rushneck stated that he believes every statistician will agree that if the objective is to determine if a level has been violated, but that level is below the level that can be measured, then the appropriate test is a one-sided test. None of the statisticians in the room disagreed with this assertion. Taft added that permit limits can fall above and below detection levels and between quantitation levels, and EPA needs to address all situations. Dr. Gibbons there are some cases in which he would disagree with that, including in the context of the usual MDL-- a one-sided test with a null hypothesis of zero--, but there also are many cases in which the one-sided test as described by Mr. Rushneck may be useful and is certainly viable, but you have to have the correct standard deviation and it has to be tested against the standard rather than against zero. Dr. Gibbons also added that as an alternative, the quantitation limit can also be used in this way, but that it is more arbitrary because 10 σ is somewhat arbitrary. If it just greater than zero, no one knows what the true concentration is and what has been exceeded. If it is quantifiable by some reasonable term, then it can be compared to the standard. Both approaches are scientifically defensible, and the decision about which to use is a policy decision that needs to be made.

Discussion of Ninth EPA Concern with AML, *Group*

EPA's ninth concern was that:

> The large number of laboratories suggested for an interlaboratory study (30) will preclude use of the AML. The use of an interlaboratory multiplier solves this problem, but an interlaboratory multiplier also can be used with the ML. Therefore, the issue is not the AML, ML, or any other quantitation limit concept, but whether an estimate of interlaboratory variability should be allowed with any of these concepts.

Mr. Rushneck led this discussion by explaining that the key point was that if you can allow an interlaboratory multiplier for the AML, you can similarly allow one for the ML. Mr. Maddelone responded on behalf of IIAG by noting there seems to be some agreement that there is a somewhat significant difference between interlaboratory variability and intralaboratory variability. He further clarified that the comment about the 30 laboratories appears to be a misinterpretation of statements that EPRI studies have had up to 30 laboratories. Ray noted that IIAG largely agrees with ASTM-2777 which states that you need to have approximately 6 laboratories remaining at the end of the study, which means that realistically approximately 10 - 11 may be needed to initiate a study.

Commenting on the phrase that "the issue is... whether an estimate of interlaboratory variability should be allowed with any of these concepts, Jim Rice argued IIAG's strong belief that interlaboratory variability *must* be allowed in order to have a sufficient understanding of data reliability in terms of the standard deviation surrounding a measured value. Mr. Rushneck responded that although everyone in the room is familiar with interlaboratory data sets showing enormous variability, the critical question is whether that variability should be allowed at all, or if instead, the ML should be used as a minimum performance criterion in order to preclude wide variability at the quantitation level. Mr. Rice responded that he is always concerned about this concept presupposes you have studied the interlaboratory variability

at this minimum performance level.

Discussion of Tenth EPA Concern with AML, *Group*

EPA's tenth concern was that:

> The AML is the concept of these times. The last concepts advanced by many of the proponents of the AML were the compliance monitoring detection level (CMDL) and compliance monitoring quantitation level (CMQL). IUPAC has now revised detection and quantitation level concepts. In 1994, the American Chemical Society attempted to advance the concepts of the reliable detection level (RDL) and reliable quantitation level (RQL). A 99 percent/95 percent interlaboratory detection estimate (99/95 IDE) has been proposed within the ASTM D-19 Committee. In an article in January 1995, the Water Environment Federation supported the practical quantitation level (PQL). EPA cannot change detection/ quantitation level concepts based on the latest desires of a single organization or group of organizations. If EPA is to change concepts, a more logical change would be to a concept advanced by a consensus organization such as IUPAC, ISO, ACS, or ASTM. EPA believes that the MDL/ML remains consistent with the concepts in use by nearly all of these organizations.

After confirming that key concept behind this concern was that the AML is the "method du jour", Mr. Maddelone led IIAG's rebuttal by stating that:

- IIAG believes the AML has evolved over many years from a cooperative effort between EPRI and other industries interested in working together to develop a scientifically defensible workable solution to this problem. This suggests that the AML is not simply the method du jour but is rather a product of evolution that reflect industry's commitment to a defensible technical solution and policy changes over time.

- IIAG believes that the argument of continuing to use the MDL instead of the AML because there are a number of different alternatives is analogous to an argument for continuing to use a slide rule instead of a computer because there are MACs, Dells, Gateways, etc.

- IIAG believes that consensus by IUPAC, ISO, ACS, ASTM and other organizations is not a valid comment because the decision should be based on sound science rather than a "popularity contest".

Mr. Telliard asked if IIAG is saying that these organizations have no standing. Mr. Nott responded that they are not saying these organizations have no standing, they are simply suggesting that the decision must be based on sound technical science. He also added that the MDL/ML is *not* consistent with the approach advocated by at least one of the organizations cited by EPA.

Mr. Maddelone added that IIAG does not believe that if one really looks at the definitions applied, that the MDL/ML really is consistent. Specifically, Mr. Maddelone cited flaws in the IUPAC approach identified by Long and Wineporter in Anal. Chem, 55, 713A, 83, where they found that if you take very well controlled data, the MDL type of approach works very well, but that in less controlled situations, they found that the MDL was 12 - 2500 times lower than the more rigorous approaches that could deal

with the propagation of errors. Mr. Maddelone added that while the ACS requires an RSD of 10%, but the ML does not drive to that level, and without running a specific study the RSD associated with a given ML is unknown. In addition, the ASTM IDE, which is being led by David Coleman, is a detection protocol that is very consistent with the principals used to calculate the AML.

Mr. Rushneck responded to Mr. Maddelone's assertion, by noting that the ACS suggests 10 standard deviations as the level of quantitation, which is consistent with IUPAC. Mr. Maddelone replied that they specifically cite an RSD of 10%, and that this is approximated by σ. Mr. Rushneck responded that EPA is saying the same thing.

In closing, Mr. Maddelone emphasized IIAG's perspective that it really makes no difference what any organizations say; what is important, however, is that EPA adopts the position that is correct. Mr. Telliard agreed, noting that if IIAG says something that is incorrect, EPA should similarly not adopt that position.

Discussion of Eleventh EPA Concern with AML, *Group*

EPA's eleventh concern was that:

> The present embodiment of the AML does not require pre-qualification of laboratories, possibly resulting in an inflated AML resulting from poorly performing laboratories. Having laboratories demonstrate that a given detection level can be achieved is a means of assuring that measurements at that detection level can be made.

Mr. Rushneck opened this discussion by noting that he and Mr. Rice had briefly touched upon the issue when addressing the question of whether it is necessary to prequalify laboratories for the interlaboratory studies performed to establish the AML. Citing Andy Eaton's (Montgomery Watson Laboratories) studies of interlaboratory variability, in which results from laboratories performing drinking water analyses varied by two orders of magnitude, Mr. Rushneck stated that without prequalification of laboratories, it is possible to end up with really wild values for the AML.

Dr. Gibbons responded that Mr. Eaton's presentation at *PittCon??* was a painful experience. According to Dr. Gibbons, the purpose of Mr. Eaton's paper was to suggest that one could conduct MDL studies in a variety of laboratories and then develop some kind of statistical bounds/interval around an "average MDL" such that most of the labs can achieve that value. However, Mr. Eaton's approach was flawed because there was no control whatsoever of the spiking concentration. Dr. Gibbons added that several spiking concentrations were used by the laboratories in Mr. Eaton's study, and in fact, if one looked at Mr. Eaton's data, it showed several mounds in the distribution. Although Mr. Eaton inferred that some of the laboratories in the outer distribution were badly functioning laboratories, a closer examination of the data suggests that some of these supposedly poor performing laboratories were actually the ones that chose the higher spike concentrations. In other words, the interval was very wide as a function of spiking concentration. Dr. Gibbons added that Mr. Eaton's sort of approach again sheds light on the fundamental issue, which is that it is critical to maintain absolute control of the spiking level. Dr. Gibbons further clarified that there is nothing wrong with using the MDL has a quality control measure, but it is important fix the spiking level so that all laboratories are in a common playing field and are on the right point on the precision curve. Mr. Ruschneck replied that this was a valid suggestion. Mr. Coleman commented that there was no statisitical basis for the algorigthm used by Mr. Eaton, so it was hard to make heads or tails of it.

Dr. Maddelone concluded this discussion by presenting IIAG's formal response to this issue. First, he noted that there is no legal basis at this time to require laboratories to be qualified by EPA, adding that there is nothing on this subject in the appendix to the 1994 guidance document. He also stated IIAG's belief that prequalification is not necessary because the standard compliance monitoring rules apply; namely, if a site-specific study is conducted for whatever reason, then the permittee is required to substantiate the basis and results of the study. Finally, Mr. Maddelone noted that the laboratories that performed in EPRI's studies were competent and qualified. Mr. Rushneck asked Mr. Maddelone how these terms were defined. Mr. Maddelone responded that they were currently using the method and certified for compliance monitoring as demonstrated by recently passing their Discharge Monitoring Report Quality Assurance (DMQ QA) analyses.

Mr. Ruschneck commented that everyone seems to be in agreement that noone wants to use poor laboratories. Mr. Maddelone agreed, adding that, on the other hand, it is unreasonable to expect to rely soley on laboratories that are in the 99th percentile. Mr. Telliard observed that, based on OST's experience, it is critical to prequalify laboratories in some way. OST, however, has no preconcieved notions of what those prequalification requirements must be, and recognizes that they may vary by program need. Mr. Telliard suggested that the National Environmental Laboratory Accredidation Committee (NELAC) may ultimately provide some resoution of this problem.

Mr. Rice commented that he had recently conducted a study for USGS to evaluate the ways in which a variety of agencies handle the issue of quality and comparability; Mr. Rice concluded that many of the agencies do a lot better than EPA in that they have very well-developed techniques to qualify laboratories. He added that EPA would do far better if it sent the samples at the MDL and determine if the results provided by the laboratory were within predefined acceptance bands. Mr. Telliard agreed that this would be useful.

Dr. McCarty asked Mr. Maddelone about an earlier comment about EPRI's studies in which samples are sent to the laboratories blind. Specifically, Dr. McCarty wanted to know what type of data are received from the laboratories in these studies. Is it merely the sample results in a printout form, or is it something that could be validated by an independent third party? Mr. Maddelone responded that EPRI receives individual measurements for each replicate. The laboratories are given instructions that they do not want the instrument to censor data; therefore, EPRI receives the laboratories' raw data that include zeros and negative numbers at the low end. EPRI then runs the raw data through the STATCALC program. Dr. McCarty observed that EPRI receives strictly concentration data and does not have information regarding calibration linearity that would enable a data user to determine why certain outliers are present. Dr. McCarty added that different applications of the same method may have slightly different calibration ranges, and the possibility exists that the sample chosen for the study at or above the upper end of the calibration curve used by one or more of the laboratories in the study. Without the calibration data, it would be difficult to recognize this problem. Mr. Maddelone deferred to Angie Grooms of Duke Power, who was one of the lab supervisors that normally sets up such studies. She replied that normally they survey the laboratories to verify that they are using the method and to determine the ranges in which they typically believe they can measure. This information is used in designing the study. Dr. McCarty responded that this approach functions as a form of prelaboratory qualification.

Discussion of Twelfth EPA Concern with AML, *Group*

EPA's twelfth concern was that:

EPA may be better served, in terms of (1) reduced effort, (2) a more user-friendly product, and (3) statistical correctness, by upgrading the MDL to correct the statistical error in documentation of the MDL at 40 *CFR* 136 and by providing more guidance for use of the MDL. Correcting the statistical error requires dividing the product of the t-statistic and the standard deviation by the square root of n, the number of measurements used to estimate the standard deviation. It should be noted that the resultant detection level would be reduced in magnitude from the existing MDL.

Mr. Maddelone formally led this discussion on behalf of IIAG. He began by commenting that the critical issue from a permittee standpoint is that they are faced with a $25,000 per day fine for violations that might be based on poor science. Therefore, any discussions of cost must factor in the cost of $25,000 per day times 30 days because, typically, these violations are based on monthly numbers. Mr. Maddelone added that these costs would easily cover the employment of additional chemists to conduct a lot of studies.

As a second point, Mr. Maddelone noted that the AML tools exist and are sufficient to allow a qualified chemist or EPA staff to compute AMLs. He added that if EPA and IIAG could agree on an approach, IIAG could work out an expert system or a hardwired system that explicitly lays out the procedure.

Finally, Mr. Maddelone noted that dividing by the square root of n does not correct any of the errors in the MDL calculation. Deferring this issue to the statisticians, Mr. Nott and Mr. Maddelone suggested that this might have been the result of a statement made by Dr. Gibbons in a paper he wrote for the Pittsburgh Conference. Dr. Gibbons expanded on this, noting that in that paper, he stated that following the MDL derivation outlined by Glaser et al leads to a confidence limit for the mean, and this confidence limit has a square root of n in it; this leads to the wrong estimator, but this could be fixed by using a tolerance bound or a prediction bound. Dr. Gibbons noted that he certainly had no intent of suggesting that anyone to divide the MDL figures by the square root of n. Dr. Kahn replied that Dr. Gibbons was not the only statistician to criticize the derivation of the MDL; statisticians within EPA also had observed problems with it. Dr. Kahn stated his belief that the deriviation outlined by Glaser et al it was an attempt by chemists in EPA's Cincinnati laboratory to approximate the ACS guidance for a limit of detection as three times the standard deviation of the noise level. He added that it does open the notion that the MDL procedure could be improved by issuing additional clarification or guidance. The bottom line of this discussion was that EPA withdrew its comment about the square root.

Mr. Telliard suggested that based on the phone calls EPA gets and on the comments made by IIAG, it was likely that some further clarification of the MDL would be issued to alleviate some of the misconceptions about the procedure. He added that these clarifications might include some of the suggestions that IIAG has made such as the use of a single spike levels. Dr. Kahn questioned whether any offering to clarify or improve upon the MDL would be acceptable to this group. Mr. Nott replied that IIAG essentially stands by what its previous statements that the AML is a constructive alternative which provides a reasonable basis for serving as a compliance threshold.

Summary of IIAG's Position

Mr. Maddelone concluded IIAG's presentation by summarizing the key points made by IIAG throughout the meeting. Specifically, IIAG believes that:

- EPA should make the right decision based on good science.

- Objective criteria are needed to select the definition of a quantitation level. IIAG presented a well-thought out list of such criteria, including properties and performance standards, at the August 1995 meeting.

- Accuracy and reliability are more important than administrative convenience, which is closely linked to the issues of complexity and cost.
  - Complexity can be addressed through the program/protocol that are used.
  - Cost is relative; it is important to consider the costs that would be imposed for exceeding a regulatory limit.

- IIAG has developed tools for determining the AML and is willing to share these tools with EPA.

He concluded by stating that the proposed AML addresses many of the shortcomings that IIAG believes exist with the ML. IIAG is simply trying to extend the basic concept that you have to use a calibration approach.

Barry's presentation

This is the end of tape 5 and probably all of tape 6. I'll leave this for Barry and Dale to write.

IIAG Demonstration of New AML Software

need to add little blurb about their demonstration

Closing Remarks

I need to come back and add Bill's closing remarks here.